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| 24113 7590 01/30/2009 PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100 | | | | |
| EXAMINER | | | | |
| KRUSE, DAVID H | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,361

Applicant(s)

PRATELLI ET AL.

Examiner

David H. Kruse

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2008 and 20 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/08/2008
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I [sic] claims 11 and 12 (Group III in the Office action mailed 8 May 2008) in the reply filed on 2 June 2008 is acknowledged. The Examiner has reevaluated the restriction requirement and has rejoined claims 1-4 and 6-10, which include the elected product (claim 6) and a method of making the elected product (remaining claims).
2. Claims 16-21 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2 June 2008.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Information Disclosure Statement

4. The listing of references in the specification on pages 23-24 is not a proper information disclosure statement. 37 CFR § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be

submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

5. The IDS filed 8 November 2006 has been considered, a signed copy is attached hereto.

Specification

6. The Abstract is objected to. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

7. The disclosure is objected to because of the following informalities: The following typographical errors are noted; page 10, line 24 "40\$", page 19, line 28 "roots ®,". As the instant specification appears to be a translation from a foreign language, Applicants are advised to review the specification for other typographical errors.

Appropriate correction is required.

8. The amendment to the specification, line 1, on 3 August 2006 is objected to because the instant Application was filed under 35 USC § 1.371, as such the instant Application is the National Stage Application of..., Applicants' claim of priority does not designate what type of priority is claimed. Also, it is the PCT application that claims priority to the French Application. An incorporation by reference to the PCT application is confusing, and it is unclear if the incorporation by reference to the French application is directed to essential material, and as Applicants have not submitted an English translation of the French application the Examiner is unable to make such a determination. See 37 CFR § 1.57.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 3, 4 and 7-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 1, the metes and bounds of "modifying the expression of a gene" at line 4 is unclear.

At claims 3, 8, 11 and 12, the limitation "at least 40% similarity" is a relative limitation that lacks a specific reference to what it is relative to. Also, the limitation "the nucleotide sequence" lacks proper antecedent basis within the claim.

Claim 7 is indefinite because the method sets forth no method steps by which the claimed invention is to be practiced. Hence, the metes and bounds of the claim are unclear.

Those claims not specifically addressed are also indefinite for being dependent from an indefinite claim.

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-4 and 6-12 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method for obtaining a transformed plant comprising modifying the expression of a gene encoding an outward potassium channel, transforming a plant cell with a gene encoding an outward potassium channel, and said method wherein the gene encodes a polypeptide sequence having at least 40% similarity with a polypeptide sequence deduced from the nucleotide sequence encoding an outward potassium channel derived from *Vitis vinifera* (grape).

Applicants describe a nucleotide sequence encoding a grape outward potassium channel polypeptide at SEQ ID NO: 1.

Applicants do not describe other nucleotide sequences encoding other outward potassium channel polypeptides.

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed. See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

13. Claims 1-4 and 6-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant transformed with and a method of using a nucleotide sequence encoding an outward potassium channel polypeptide that is encoded by SEQ ID NO: 1, does not reasonably provide enablement for a method of modifying the expression of any gene encoding an outward potassium channel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants claim a method for obtaining a transformed plant comprising modifying the expression of a gene encoding an outward potassium channel, transforming a plant cell with a gene encoding an outward potassium channel, and said method wherein the gene encodes a polypeptide sequence having at least 40% similarity with a polypeptide sequence deduced from the nucleotide sequence encoding an outward potassium channel derived from *Vitis vinifera* (grape).

Applicants teach a nucleotide sequence encoding a grape outward potassium channel polypeptide at SEQ ID NO: 1.

Applicants do not teach other nucleotide sequences encoding other outward potassium channel polypeptides.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of

working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Instant claims 1, 2, 4, 6 and 7 are directed to modifying any outward potassium channel in any plant or plant cell. Applicants only provide guidance on how to make and use a grape outward potassium channel (SEQ ID NO: 1). It is unclear from the instant specification how predictable it is to modify a phenotype related to a size or the organic acid composition of a storage organ of a plant by modifying the expression of other genes encoding outward potassium channels without undue trial and error experimentation because Applicants only provide guidance on how to make and use one species.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 2, 4, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ishitani *et al* (WO 01/45495 A2).

Ishitani *et al* disclose a method of modifying the expression of a gene encoding an outward potassium channel in one or more cells of a plant including the cells of a storage organ and cells in the tissues supplying the storage organ at claim 23 on page 64. Ishitani *et al* disclose said method using a “super promoter” operably linked to said

gene at Figure 4. Ishitani *et al* disclose the method steps of transforming at least one cell of the plant, selecting the at least one transformed cell and regenerating a transformed plant in Example 10 on pages 55-56. Ishitani *et al* disclose use of the CaMV 35S promoter at page 28, 1st paragraph, to express said gene within the whole plant. Hence, the method disclosed by Ishitani *et al* would overexpress said gene in one or more cells of a plant including the cells of a storage organ and cells in the tissues supplying the storage organ. Ishitani *et al* disclose a method of measuring expression of said gene in tissues supplying a storage organ at Example 17 on page 60. Given that the invention of Ishitani *et al* increases stress tolerance in a transgenic plant, in a stress environment said transgenic plant would have a modified phenotype relating to a size of a storage organ of said transgenic plant relative to a non-transgenic plant of the same species. Plants comprise many storage organs, such as fruit, roots, tubers, or rhizomes, for example.

Claim Rejections - 35 USC § 103

16. Claims 3 and 8-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ishitani *et al* (WO 01/45495 A2) in view of Pratelli *et al* (2002, Plant Physiology 128: 564-577).

The teachings of Ishitani *et al* are outlined above. Ishitani *et al* also teach detection of mRNA in a transgenic plant at Example 9 on pages 53-54.

Ishitani *et al* do not teach a gene encoding a *Vitis Vinifera* outward potassium channel.

Pratelli *et al* teach a nucleotide sequence encoding a *Vitis Vinifera* outward potassium channel (see legend for Figure 1 on page 566). Said nucleic acid sequence encodes a polypeptide sequence 100% identical to the polypeptide encodes by Applicants' SEQ ID NO: 1.

It would have been *prima facie* obvious to modify the teachings of Ishitani *et al* using the nucleic acid sequence encoding a *Vitis vinifera* outward potassium channel taught by Pratelli *et al*. Pratelli *et al* teach "The identification of the *SIRK* gene is therefore likely to provide the first molecular tool for investigating these aspects of berry development" (page 573, right column, 1st paragraph). Given the success of Ishitani *et al*, one of ordinary skill in the art at the time of Applicants' invention would have had a reasonable expectation of success.

Conclusion

17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
28 January 2009